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10/527,662	03/11/2005	Joel Vandekerckhove	BJS-4465-6	7309

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EXAMINER	
FOSTER, CHRISTINE E	
ART UNIT	PAPER NUMBER
1641	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

Office Action Summary	Application No.	Applicant(s)	
	10/527,662	VANDEKERCKHOVE ET AL.	
	Examiner	Art Unit	
	Christine Foster	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2010 and 12 October 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-5,13,14 and 17-36* is/are pending in the application.

4a) Of the above claim(s) *19 and 30-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-5,13,14,17,18 and 20-29* is/are rejected.

7)☒ Claim(s) *17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 February 2008* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/21/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. In the reply of 6/21/2010, claims 1, 6-7, and 15-16 were canceled. Claims 2-5 and 13-14 were amended. New claims 17-36 were added.

Election/Restrictions

2. Applicant's election with traverse of **benzoyl-penicilline** as the species of molecule in the reply filed on 10/12/2010 is acknowledged. The traversal is on the ground(s) that the pending claims have unity of invention because they are linked by the special technical feature of being able to isolate unknown interaction partners. This is not found persuasive because as discussed in the restriction requirement on page 5, alternatives of Markush group are regarded as being of a similar nature only when (A) all alternatives have a common property or activity; AND (B)(1) a common structure is present, that is, a significant structural element is shared by all of the alternatives; OR (B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains. See Annex B, Unity of Invention, of the PCT Administrative Instructions.

In this regard, Applicant further that any and all molecules would be expected to behave in the same way, and would therefore belong to a recognized class of chemical compounds as per B(2) above (Reply, page 3). This is not found persuasive because the claims currently recite that the molecule interacts via binding to an **active site**, which is defined instantly as the specific area on the surface of a protein (e.g. an enzyme or receptor), to which a compound (e.g. a substrate, a ligand, a drug or a drug analogue or a drug derivative) can bind resulting in a change in the

configuration of the protein. However, not all molecules interact by binding to an active site; and not all molecules that do interact by binding to an active site would necessarily result in a change in the configuration of the protein. Thus, any and all molecules would not be expected to behave in the same way.

For reasons of record, it is maintained that the chemical compounds of **molecules** are not regarded as being of similar nature because: (1) the alternatives do not all share a common structure and (2) the alternatives do not all belong to a recognized class of chemical compounds.

Applicant further argues that none of the claims recite a Markush group of alternative molecules (Reply, page 3). This is not found persuasive because the claims clearly encompass a genus of molecules, as evidenced by Applicant's indication in the instant reply that not all claims read on the elected species of molecules.

The requirement is still deemed proper and is therefore made FINAL.

3. Applicant states that claims 2-5, 13-14, 17-18, and 20-29 read on the elected species. Accordingly, claims 19 and 30-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/12/2010.

4. Accordingly, claims 2-5, 13-14, and 17-36 are pending in the application, with claims 19 and 30-36 currently withdrawn. Claims 2-5, 13-14, 17-18, and 20-29 are subject to examination below.

Objections/ Rejections Withdrawn

5. The rejections under §102 and §103 as set forth in the Office action mailed 2/22/2010 are withdrawn in response to Applicant's cancellation of claims 1 and 15-16. Newly added independent claim 17 requires that the molecule bind to an "active site" of the protein or peptide interaction partner. As defined instantly, the "active site" refers to the specific area on the surface of a protein (e.g. an enzyme or receptor), to which a compound (e.g. a substrate, a ligand, a drug or a drug analogue or a drug derivative) can bind resulting in a change in the configuration of the protein. The Creighton et al. and Cruickshank references do not specifically teach whether amino acid labeling would involve the active site of peptides, or whether labeling would be accompanied by a change in the configuration or conformation of the peptides.

Priority

6. The present application was filed as a National Stage (371) entry of PCT Application No. PCT/EP03/50402, filed 9/11/2003. Acknowledgment is also made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) to Application No. 02078801.4, filed on 9/12/2002 in Europe.

Drawings

7. The drawings filed 2/22/2008 are objected to because in Figure 9, the text at the upper right hand corner of the Figure is cut off. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate

prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

8. Claim 17 is objected to because of the following informalities:

9. Claim 17, lines 7-9 present confusion for the following reasons. This portion of the claim refers to the formation of "molecule-interaction partner complexes, wherein molecules thereof do interact with a protein or peptide to form **molecule-interaction partner complexes therein**". It is unclear what the boldfaced term "therein" is referring back to. From the sentence structure this would seem to refer back to the molecule-interaction partner complexes earlier recited, yet this would lead to a circular recitation of molecule-interaction partner complexes within molecule-interaction partner complexes. Clarification is needed.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 2-5, 13-14, 17-18, and 20-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims recite a method of isolating at least one interaction partner of a molecule, where the interaction partner is a protein or peptide that is initially present in a complex mixture. Isolation is accomplished by adding the molecule to the mixture. The claims recite that the molecule is "capable of specifically and stably interacting with a protein or peptide [in the mixture] to form molecule-interaction partner complexes". In addition, the claims require that "the specificity of the interaction…is determined by binding to an active site of the protein or peptide".

The claimed methods therefore invoke the use of molecules that must possess certain functional characteristics, namely the ability to specifically and stably interact with at least one protein or peptide by binding to the **active site** of the protein or peptide. As defined instantly, the "active site" refers to the specific area on the surface of a protein (e.g. an enzyme or receptor), to which a compound (e.g. a substrate, a ligand, a drug or a drug analogue or a drug derivative) can bind resulting in a change in the configuration of the protein. Further, the molecule must be

capable of being "chemically and/or enzymatically alter[ed]" in a way that affects its elution time when present as a molecule-interaction partner complex.

However, the specification fails to disclose what structural features are responsible for imparting these desired properties, and therefore fails to disclose any correlation between structure and function.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed. The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the application. These include “level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention.” MPEP 2163.

For a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a

representative number of species to adequately describe a broad generic. In Gostelli, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli 872, F.2d at 1012, 10 USPQ2d at 1618.

In the instant case, the specification discloses certain examples of suitable molecules that may specifically bind to the active sites of proteins. For example, the specification proposed that a Lys-containing peptide to be used to interact with G-actin via the catalytic action of a transglutaminase (published application, [0074]). In addition, the specification contemplates fluorosulfenylbenzyol adenosine (FSBA) in order to interact with ATP-binding proteins [00084].

However, the specification does not adequately describe the genus of molecules having the requisite functional characteristics, since it is not disclosed what structural features common to the genus are responsible for function. In particular, the specification does not identify what elements of the disclosed species are critical for maintaining the ability to specifically and stably interacting with the active site of a protein or peptide. Similarly, the specification does not identify any partial structural features that are responsible for imparting the ability to be "chemically and/or enzymatically alter[ed]" in a way that affects its elution time when the molecule is present as a molecule-interaction partner complex.

As such, it is not possible to envisage what other molecules might possess the necessary functional characteristics. The disclosure of a number of disparate chemical compounds does not in this case lead one of ordinary skill in the art to envisage the broad genus, as there is no disclosed common structure or other unifying theme that would serve to identify the members of the genus. The disclosed species cannot be extrapolated to the broad genus.

Regardless whether a compound is claimed per se or a method is claimed that entails the use of the compound, the inventor cannot lay claim to that subject matter unless he can provide a description of the compound sufficient to distinguish infringing compounds from non-infringing compounds, or infringing methods from non-infringing methods. University of Rochester v. G.D. Searle & Co., 358 F.3d 916, 926 (Fed. Cir. 2004).

In the instant case, it is further noted that the claimed "complex mixture" would encompass mixtures of varying compositions. As such, it is reasonable to assume that a compound might interact via active site binding in some complex mixtures, while interacting with proteins in other ways in other complex mixtures. In other words, the nature of binding depends not only on the nature of the molecule, but also on the nature of the interacting protein/peptide. Without reference to objective structural features common to the genus, it is not possible to determine what molecules fall within the claimed genus and what compounds do not.

Moreover, the claims encompass isolation of unknown interaction partners (see Applicant's reply of 10/12/2010 at page 2). In other words, the claims would encompass methods of screening complex mixtures for the presence of unknown proteins or peptides in a complex mixture, where the unknown proteins or peptides bind to the molecule via their active site and undergo a change in configuration as a result.

Molecules may specifically bind to proteins or peptides in various ways. Not all specific binding interactions involve active sites, and not all binding events result in a change in the configuration of the protein or peptide. See for example Gunasekaran et al. (J. Mol. Biol. (2007) 365, 257–273), which teaches that not all ligand binding events cause proteins to undergo a conformational change (see, e.g., the title).

As such, it is not predictable an added molecule would necessarily interact by binding to an **active site** and change the configuration of the involved protein or peptide as claimed. The specification does not disclose what structural features would identify those molecules that would necessarily interact via binding to an active site with concomitant change in configuration, as opposed to molecules that would interact via other forms of binding.

In particular, newly added claim 18 recites that the molecule comprises a chemical structure by which the molecule binds to an active site of the protein or peptide. However, the specification does not provide partial structure or other identifying characteristics that would allow one to envisage what chemical structures would possess this functional property. The identification of a molecule or of a chemical structure therein by reference to a desired functional property alone is insufficient description.

Similarly, newly added claim 20 requires that interaction only occurs when the protein or peptide is "in a particular conformation". However, the specification fails to disclose any structural features that are shared by those molecules capable of ensuring this desired result. It is unknown which of the many known molecules would be able to interact with a protein/peptide only when is in a particular conformation.

There specification does not disclose how to ensure that an added molecule would only interact with the active sites of interaction partners, and change their configuration in the process of binding.

The claimed method is therefore analogous to the method claimed in University of Rochester and, just as in that case, “the inventor cannot lay claim to that subject matter unless he can provide a description of the compound sufficient to distinguish infringing compounds from

non-infringing compounds, or infringing methods from non-infringing methods." University of Rochester, 358 F.3d at 926.

Furthermore, as discussed above the nature of a binding event depends both on the identity of the molecule as well as the identity of the interacting protein/peptide. Gunasekaran et al. (discussed above) provide evidence that the nature of an interacting protein/peptide influences whether the protein/peptide will undergo a conformational change upon ligand binding (see especially the abstract). The claims do not specify the identity of either the molecule or of the interaction partner, and the molecules may be added to complex mixtures of varying compositions. As such, even in the case of the disclosed examples involving known molecules, it is not predictable that these molecules would necessarily interact via active site binding and produce a conformational change in any protein or peptide with which the molecules interact.

For example, the elected species of benzoyl penicillin is suggested as a molecule capable of specifically interacting with bacterial DD aminotranspeptidase (Example 1). However, benzoyl penicillin is also known to participate in nonspecific binding interactions (see Suginaka et al., Antimicrob Agents Chemother. 1974 Dec;6(6):672-5, who teach that benzoyl penicillin (termed "penicillin G" in the reference) binds nonspecifically to cells (see especially page 675, left column).

Therefore, it is not predictable that adding a molecule to a complex mixture would result only in binding to an active site with accompanying conformational change. Because the composition of the complex mixture may vary, it is not predictable that an added molecule (even one known to specifically bind to the active site of a given protein/peptide) would necessarily interact in this manner with any complex mixture.

In addition, new claim 28 recites that the interaction partner isolated may be specific molecules such as a nucleoprotein, a glycopeptide, a steroid receptor, a ligase, etc. However, the specification does not disclose what structural features would impart the ability to selectively isolate these particular types of interaction partners.

Without reference to objective structural features common to the genus, it is not possible to determine what molecules fall within the claimed genus and what compounds do not. Because the specification does not disclose what molecules would have the necessary functional characteristics, the claimed genus of molecules has not been adequately described.

For all of these reasons, the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

12. Claims 2-5, 13-14, 17-18, and 20-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims recite a method of isolating at least one interaction partner of a molecule, where the interaction partner is a protein or peptide that is initially present in a complex mixture. Isolation is accomplished by adding the molecule to the mixture. The claims recite that the molecule is "capable of specifically and stably interacting with a protein or peptide [in the mixture] to form molecule-interaction partner complexes". In addition, the claims require that

"the specificity of the interaction…is determined by binding to an **active site** of the protein or peptide" (emphasis added).

The claimed methods therefore invoke the use of molecules that must possess certain functional characteristics, namely the ability to specifically and stably interact with at least one protein or peptide by binding to the **active site** of the protein or peptide. As defined instantly, the "active site" refers to the specific area on the surface of a protein (e.g. an enzyme or receptor), to which a compound (e.g. a substrate, a ligand, a drug or a drug analogue or a drug derivative) can bind resulting in a change in the configuration of the protein. Further, the molecule must be capable of being "chemically and/or enzymatically alter[ed]" in a way that affects its elution time when present as a molecule-interaction partner complex.

The claims are being evaluated in light of the elected species involving the molecule benzoyl penicillin. The specification discloses a prophetic example in which this molecule could be used to isolate bacterial DD aminotranspeptidase (see Example 1). The specification does not explicitly state that benzoyl penicillin binds to the active site of the enzyme resulting in a change in configuration, but does disclose that interaction involves the formation of an acyl-enzyme adduct. It is therefore likely that benzoyl penicillin would interact with bacterial DD aminotranspeptidase by binding to the enzyme active site, and it is also possible that the enzyme would undergo a change in configuration as a result.

However, the claims are not limited to the isolation of bacterial DD aminotranspeptidase using benzoyl penicillin. Rather, the claims encompass isolation of unknown interaction partners (see Applicant's reply of 10/12/2010 at page 2). In other words, the claims would encompass methods of screening complex mixtures for the presence of unknown proteins or peptides in a

complex mixture, where the unknown proteins or peptides bind to the molecule via their active site and undergo a change in configuration as a result.

As discussed above, molecules may specifically bind to proteins or peptides in various ways. Not all specific binding interactions involve active sites, and not all binding events result in a change in the configuration of the protein or peptide. See for example Gunasekaran et al. (J. Mol. Biol. (2007) 365, 257–273), which teaches that not all ligand binding events cause proteins to undergo a conformational change (see, e.g., the title).

As such, it is not predictable an added molecule would necessarily interact by binding to an **active site** and change the configuration of the involved protein or peptide as claimed. Given that the claimed methods may be performed on various "complex mixtures" of varying compositions, a compound might interact via active site binding in some complex mixtures, while interacting with proteins in other ways in other complex mixtures.

Further, Gunasekaran et al. (discussed above) provide evidence that the nature of an interacting protein/peptide influences whether the protein/peptide will undergo a conformational change upon ligand binding (see especially the abstract). The claims do not specify the identity of either the molecule or of the interaction partner, and the molecules may be added to complex mixtures of varying compositions. As such, even in the case of the elected species of benzoyl penicillin, it is not predictable that this molecule would necessarily interact via active site binding and produce a conformational change in any protein or peptide with which it interacts. The specification lacks working examples in which benzoyl penicillin was actually used to isolate any interaction partner, and in particular an interaction partner initially present as part of a complex mixture such as tears or saliva, for example.

The breadth of the claims is also at issue. In addition to benzoyl pencillin, the claims encompass a genus of molecules capable of interacting with an active site of a protein or peptide resulting in a change in configuration. The molecules must also be capable of being "chemically and/or enzymatically alter[ed]" in a way that affects its elution time when present as a molecule-interaction partner complex. Although the specification suggests four particular molecules to use, these molecules are not linked by any common structure or unifying theme (see written description rejection above). As such, the disclosed examples of molecules do not lead one of ordinary skill in the art to other members of the genus, and therefore lacks guidance in carrying out the claimed invention. One cannot extrapolate the teaching of the specification to the scope of the claims because said teachings represent insufficient guidance and objective evidence to predictably enable the use of the claimed invention.

In addition, new claim 28 recites that the interaction partner isolated may be specific molecules such as a nucleoprotein, a glycopeptide, a steroid receptor, a ligase, etc. However, the specification does not disclose a repeatable process for selectively isolating such particular types of interaction partners. For example, the specification does not disclose molecules that could be used to selectively isolate nuclear proteins.

In summary, it is not predictable that adding a molecule to a complex mixture would result only in binding to an active site with accompanying conformational change. Because the composition of the complex mixture may vary, it is not predictable that an added molecule (even one known to bind to the active site of a given protein/peptide) would necessarily interact in this manner with any complex mixture. Despite such unpredictability, the specification lacks

guidance with regard to how to ensure that only interaction partners that interact in this particular are isolated by the claimed methods.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 2-5, 13-14, 17-18, and 20-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15. Claim 17 recites the limitation "the same non-altered molecule-interaction partner complex in the second chromatographic separation" in lines 22-23. There is insufficient antecedent basis for this limitation in the claim.

16. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in Ex parte Wu, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of Ex parte Steigewald, 131 USPQ 74 (Bd. App. 1961); Ex parte Hall, 83 USPQ 38 (Bd. App. 1948); and Ex parte Hasche, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 28 recites the broad recitation

"polypeptide", and the claim also recites a nucleoprotein, a glycopeptide, an enzyme, a peptide ligand, etc. which are narrower statements of the range/limitation. Similarly, the claim also recites the broad term "enzyme" as well as specific types of enzymes (hydrolase, ligase, etc.) which are narrower statements of the range/limitation.

Response to Arguments

17. Applicant's arguments with respect to claims 1-7 and 13-16 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Foster whose telephone number is (571) 272-8786. The

examiner can normally be reached on M-F 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, can be reached at (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christine Foster/
Examiner, Art Unit 1641

/Mark L. Shibuya/
Supervisory Patent Examiner, Art Unit 1641